

STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
Vis-U-All II Self Seal Pouch

1. Device NameTrade Name: Vis-U-All Self Seal Pouch

JCT 12 2007

Common/usual Name: Sterilization pouch

Classification Name: Sterilization wrap (21 CFR 880.6850 Product Code KCT).

2. Predicate Device

- Surgicot Pouches, Peel Open, Breathable (K771032)
- Surgipeel Self Seal Packaging System (K820302)

3. Description of Device

The proposed Vis-U-All Self Seal Pouch is a Tyvek/plastic film sterilization containment pouch designed for devices to be sterilized by the health care provider by the AMSCO® V-PRO 1 Low Temperature Sterilization System. It permits sealing of the pouch without need of heat-sealing equipment. The purpose of this submission is to demonstrate the Vis-U-All Self Seal Pouch is qualified for use in the AMSCO® V-PRO 1 Low Temperature Sterilizer. The 510(k) number for the AMSCO® V-PRO 1 Low Temperature Sterilizer is K062297, cleared on October 4, 2007.

4. Intended Use

The Vis-U-All Self Seal Pouch is a sterilization containment pouch designed for devices to be sterilized by the health care provider by the AMSCO® V-PRO 1 Low Temperature Sterilization System. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.

5. Description of Safety and Substantial Equivalence

The materials of composition for the Vis-U-All Self Seal Pouch have not changed in their composition from the predicate, K771032. The plastic film (polymylar) thickness has changed to 2.0mil. The device has no chemical indicators.

Performance testing of the Vis-U-All Self Seal Pouch demonstrated that the proposed pouch is qualified for use in the AMSCO® V-PRO 1 Low Temperature Sterilizer and is as safe, as effective, and performs the same as the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 12 2007

Patrick J. McCullagh, Ph.D.
Vice President
STERIS, Corporation
5960 Heisley Road
Mentor, Ohio 44060-1834

Re: K070765
Trade/Device Name: Vis-U-All Self Seal Pouch
Regulation Number: 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: September 12, 2007
Received: September 13, 2007

Dear Dr. McCullagh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
Vis-U-All Self Seal Pouch

Indications for Use

510(k) Number (if known): K070765

Device Name: Vis-U-All Self Seal Pouch

Indications For Use:

The Vis-U-All Self Seal Pouch is a sterilization containment pouch designed for devices to be sterilized by the AMSCO V-Pro 1 Low Temperature Sterilization System. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.

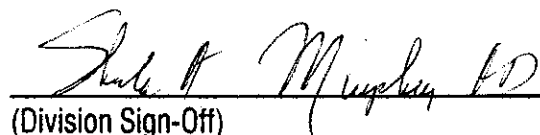
Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X_____
(21 CFR 801 Subpart C)

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IF NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Anesthesiology General Hospital
Infection Control, Dental Devices

510(k) Number: K070765

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